

### **REMARKS**

Prior to the instant response, claims 35, 40-41, 54-55, 64, 66, and 73-80 were pending in the application. By amendment herein, claim 35 has been amended. No claims have been added or cancelled. Thus, claims 35, 40-41, 54-55, 64, 66, and 73-80 remain pending.

#### **I. Claim Rejections Under 35 U.S.C. 103**

In the Office Action of November 6, 2009, the Examiner rejected the pending claims as being unpatentable over Eggensperger et al., i.e., U.S. Patent No. 5,276,047 ("D1"), in view of Ofusu-Asante et al., i.e., U.S. Patent No. 6,387,856 ("D2"). For the reasons below, the claims exclude the presence of BIT, and thus are patentable over D1.

Independent claim 35 has been amended to recite that "the solution is non-dangerous in accordance with European Dangerous Preparations Directive (99/45/EC) and Dangerous Substances Directive (67/548/EEC)." Support for this amendment may be found at PARA. 0030 of the published application.

As previously shown, the central focus of D1 is the use of BIT. *See*, pages 8-9 of the October 2, 2009, Amendment and Response. Since BIT is listed as dangerous per the EU regulations, one of ordinary skill in the art would not have used the solution of D1 as a basis for creating the presently claimed non-dangerous cleaning solution.

As shown in Appendix A, page 6, under the claimed EU regulations, the chemical compound BIT (i.e., 1,2-benzisothiazolin-3-one; CAS No. 2634-33-5) has been categorized as "**Dangerous** for the environment" (emphasis added). The "EC Safety Classification" for BIT is: "S24, S26, S37/S39, S61". Per pages 8-10 of Appendix A, these safety codes are defined as:

- S24 - Avoid contact with skin
- S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
- S37/S39 - Wear suitable protective clothing and eye/face protection
- S61 - Avoid release to the environment. Refer to special instructions /Safety data sheets

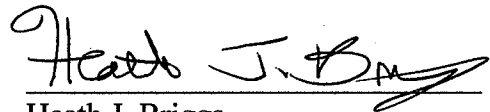
As shown on page 6 of Appendix A, BIT is also potentially a problem for "Reproduction / development effects", and is listed as "harmful" and as an "irritant".

Based on the "danger" to the environment, the "harmful" or "irritant" affect to humans, and the potential "[r]eproduction / development effects" of BIT, one of ordinary skill in the art would not consider the BIT-containing solution of D1 an acceptable starting point for making a "non-dangerous" cleaning solution, as presently claimed. Therefore, the pending claims are patentable over D1.

#### **IV. Conclusion**

Having responded to all rejections set forth in the outstanding Office Action, it is submitted that all pending claims are in condition for allowance, and notice to that effect is respectfully solicited.

Respectfully submitted,



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# APPENDIX A

**1,2-benzisothiazolin-3-one**

\*\* IPX \*\* BIT \*\* benzisothiazolin \*\* Translations



Environmental Fate - Ecotoxicology - Human Health - A to Z Index - Home - FOOTPRINT

**GENERAL INFORMATION**

**Description:** Substance with biocidal, bactericidal and fungicidal properties that is sometimes used as a preservative in product formulations.

**Introduction:** -

**EC Directive 91/414:**

Status	None - not a ppp
Dossier rapporteur/co-rapporteur	Not applicable
Date inclusion expires	Not applicable

Approved for use (✓) or known to be used (\*) in the following European countries:



AT BE BG CY CZ DE DK EE ES FI FR GR HU IE IT LT LU LV MT NL PL PT RO SE SI SK UK

\* \* \* \* \*


Also registered in: Canada, USA

**General status:**




Pesticide Type	Microbiocide, Other product constituent, Additive
Other Constituent Type	Preservative
Chemical Group	Isothiazolone
Mode of Action	Inert
CAS RN	2634-33-5
EC Number	220-120-9
CIPAC Number	-
US EPA Chemical code	098901
Chemical Formula	C <sub>7</sub> H <sub>5</sub> NOS
SMILES	c12c(cccc2)s[nH]c1=O
International Chemical Identifier (InChI)	InChI=1/C7H5NOS/c9-7-5-3-1-2-4-6(5)10-8-7/h1-4H,(H,8,9)
Structure diagram available?	Yes
Molecular Mass (g mol <sup>-1</sup> )	151.18
IUPAC Name	1,2-benzisothiazol-3(2H)-one

CAS Name	1,2-benzisothiazolin-3-one
Other status information	-
Herbicide Resistance (HRAC) Classification	Not applicable
Insecticide Resistance (IRAC) Classification	Not applicable
Fungicide Resistance (FRAC) Classification	Not applicable
Physical State	Very pale yellow to brown coloured crystals

## Formulations:

Property 	Value
Example manufacturers of products using this active	<ul style="list-style-type: none"> <li>• Sigma-Aldrich</li> <li>• Dow</li> </ul>
Example products using this active	<ul style="list-style-type: none"> <li>• Proxel</li> <li>• Nipacide</li> <li>• Troysan</li> <li>• Vanquish 100</li> <li>• Proxel</li> </ul>
Associated substances	<ul style="list-style-type: none"> <li>• lambda-cyhalothrin</li> <li>• fluazinam</li> </ul>
UK LERAP status	Not applicable
Formulation and application details	-




## ENVIRONMENTAL FATE

Property 	Value	Source/Quality Score/Other Information 	Interpretation 
Solubility - In water at 20°C (mg l <sup>-1</sup> )	0.5	E3	Low
Solubility - In organic solvents at 20°C (mg l <sup>-1</sup> )	-	-	-
Melting Point (°C)	156	E3	-
Boiling Point (°C)	-	-	-
Degradation point (°C)	-	-	-
Flashpoint (°C)	-	-	-
Octanol-water partition coefficient at pH 7, 20°C	P: - Log P: -	-	-
Bulk density (g ml <sup>-1</sup> )/Specific gravity	1.17	P3	-

Dissociation constant (pKa) at 25°C	-	-	-
Note:			
Vapour pressure at 25°C (mPa)	15.065	E3	Volatile
Henry's law constant at 25°C (Pa m <sup>3</sup> mol <sup>-1</sup> )	-	-	-
Henry's law constant at 20°C (dimensionless)	1.87 X 10 <sup>-03</sup>	Calculated	Volatile
Soil degradation (days) (aerobic)	DT50 (typical):	-	-
	DT50 (lab at 20°C):	-	-
	DT50 (field):	-	-
	DT90 (lab at 20°C):	-	-
	DT90 (field):	-	-
	Note:	-	-
Aqueous photolysis DT50 (days) at pH 7	Value: Stable	Q2	Stable
	Note:	-	-
Aqueous hydrolysis DT50 (days) at 20°C and pH 7	Value: -	-	-
	Note: -	-	-
Water-Sediment DT50 (days)	-	-	-
Water phase only DT50 (days)	-	-	-
GUS leaching potential index	-	-	-
SCI-GROW groundwater index (µg l <sup>-1</sup> ) for a 1 kg ha <sup>-1</sup> or 1 l ha <sup>-1</sup> application rate	Value: -	-	-
	Note: -	-	-
Potential for particle bound transport index	-	-	-
Koc - Organic-carbon sorption constant (ml g <sup>-1</sup> )	-	-	-
	pH sensitivity:		
	Note:		
Freundlich isotherm Kf:	-	-	-
	1/n:	-	-
	Note:	-	-

Maximum UV-vis absorption L -  
 $\text{mol}^{-1} \text{cm}^{-1}$

## ECOTOXICOLOGY

Property 	Value	Source/Quality Score/Other Information 	Interpretation 
Bio-concentration factor	BCF: -	-	-
	CT50 (days): -	-	-
Bioaccumulation potential	-	-	-
Mammals - Acute oral LD50 ( $\text{mg kg}^{-1}$ )	1020	E3 Rat	Moderate
Mammals - Short term dietary NOEL ( $\text{mg kg}^{-1}$ ):	-	-	-
	(ppm diet): -	-	-
Birds - Acute LD50 ( $\text{mg kg}^{-1}$ )	617	E3 <i>Colinus virginianus</i>	Moderate
Birds - Short term dietary (LC50/LD50)	-	-	-
Fish - Acute 96 hour LC50 ( $\text{mg l}^{-1}$ )	1.6	F4 <i>Oncorhynchus mykiss</i>	Moderate
Fish - Chronic 21 day NOEC ( $\text{mg l}^{-1}$ )	-	-	-
Aquatic invertebrates - Acute 48 hour EC50 ( $\text{mg l}^{-1}$ )	4.4	F4 <i>Daphnia magna</i>	Moderate
Aquatic invertebrates - Chronic 21 day NOEC ( $\text{mg l}^{-1}$ )	-	-	-
Aquatic crustaceans - Acute 96 hour LC50 ( $\text{mg l}^{-1}$ )	-	-	-
Sediment dwelling organisms - Acute 96 hour LC50 ( $\text{mg l}^{-1}$ )	-	-	-
Sediment dwelling organisms - Chronic 28 day NOEC, static, water ( $\text{mg l}^{-1}$ )	-	-	-
Sediment dwelling organisms - Chronic 28 day NOEC, sediment ( $\text{mg kg}^{-1}$ )	-	-	-
Aquatic plants - Acute 7 day EC50, biomass ( $\text{mg l}^{-1}$ )	-	-	-
Algae - Acute 72 hour EC50,	-	-	-




growth (mg l<sup>-1</sup>)Algae - Chronic 96 hour NOEC, -  
growth (mg l<sup>-1</sup>)Honeybees - Acute 48 hour -  
LD50 (µg bee<sup>-1</sup>)Earthworms - Acute 14 day -  
LC50 (mg kg<sup>-1</sup>)Earthworms - Chronic 14 day -  
NOEC, reproduction (mg kg<sup>-1</sup>)Other soil macro- LR50 / -  
organisms - e.g. EC50 / -  
Collembola NOEC / -  
% EffectOther arthropod (1) LR50 g -  
ha<sup>-1</sup>; -  
% -  
Effect: -Other arthropod (2) LR50 g -  
ha<sup>-1</sup>; -  
% -  
Effect: -

Soil micro-organisms -

Mesocosm study NOEAEC -  
data mg l<sup>-1</sup>; -NOEAEC -  
mg l<sup>-1</sup>; -

## HUMAN HEALTH AND PROTECTION

## General:

Property 	Value	Source/Quality Score/Other Information 	Interpretation 
Mammals - Acute oral LD50 (mg kg <sup>-1</sup> )	1020	E3 Rat	Moderate
Mammals - Dermal LD50 (mg kg <sup>-1</sup> body weight)	> 2000	E3 Rat	-
Mammals - Inhalation LC50 (mg l <sup>-1</sup> )	0.1	E3 Rat	-
ADI - Acceptable Daily Intake (mg kg <sup>-1</sup> bw day <sup>-1</sup> )	-	-	-
ARfD - Acute Reference Dose (mg kg <sup>-1</sup> bw day <sup>-1</sup> )	-	-	-
AOEL - Acceptable Operator	-	-	-



Exposure Level - Systemic (mg  
kg<sup>-1</sup>bw day<sup>-1</sup>)

Dermal penetration studies (%) - - -

Dangerous Substances Directive  
76/464 - - -

Exposure Limits - - -

Exposure Routes Public: -

Occupational: [May be absorbed through the skin.]

Examples of Value: -

European MRLs  
(mg kg<sup>-1</sup>)

Note: For the EU pesticides database click here

Drinking Water MAC (µg l<sup>-1</sup>) - - -

### Health issues:

Carcinogen	Endocrine disrupter	Reproduction development effects	Acetyl cholinesterase inhibitor	Neurotoxicant	Respiratory tract irritant	Skin irritant	Eye irritant
X	-	?	X	X	✓	✓	✓
General human health issues [Immunotoxicant], [Possible skin sensitiser], [May cause allergic dermatitis], [Harmful if ingested], [May damage eyes]							

✓ : Yes, known to cause a problem

X : No, known not to cause a problem

☆ ? : Possibly, status not identified

- : No data

### Handling issues:

Property	Value	Source/Quality Score/Other Information	Interpretation
General	[Prevent generation of dust], [Corrosive]		
☆ EC Risk Classification	[Xn - Harmful: R22, R41], [Xi - Irritant: R38, R43], [N - Dangerous for the environment: R50]		
☆ EC Safety Classification	S24, S26, S37/39, S61		
WHO Classification	NL	-	Not listed
US EPA Classification (formulation)	No consensus across products or no products available	-	-
UN Number	Usually 3077		
Waste disposal & packaging	-		

### TRANSLATIONS

Language	Name
English	1,2-benzisothiazolin-3-one
French	-
German	-
Danish	-
Italian	-
Spanish	-
Greek	-
Slovenian	-
Polish	-
Swedish	-
Hungarian	-
Dutch	-

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Site last updated: Monday 29 November 2010

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## EU Safety Phrases

Safety-phrases (also known as S-phrases) are defined in Annex II of EU Directive 67/548/EEC as amended by EU Directive 2001/59/EC which is concerned with identifying special risks attributed to dangerous substances and preparations. Whilst these phrases were developed for Europe they are used and recognised in many countries throughout the world.

### Single Codes

S1	Keep locked up.
S2	Keep out of the reach of children.
S3	Keep in a cool place.
S4	Keep away from living quarters.
S5	Keep contents under ... <i>(appropriate liquid to be specified by the manufacturer)</i> .
S6	Keep under ... <i>(inert gas to be specified by the manufacturer)</i> .
S7	Keep container tightly closed.
S8	Keep container dry.
S9	Keep container in a well-ventilated place.
S10	<i>Deleted.</i>
S11	<i>Deleted.</i>
S12	Do not keep container sealed.
S13	Keep away from food, drink and animal feeding stuffs.
S14	Keep away from ... <i>(incompatible materials to be indicated by the manufacturer)</i> .
S15	Keep away from heat.
S16	Keep away from sources of ignition – No smoking.
S17	Keep away from combustible material.
S18	Handle and open container with care.
S19	<i>Deleted.</i>
S20	When using do not eat or drink.
S21	When using do not smoke.
S22	Do not breathe dust.
S23	Do not breathe gas/fumes/vapour/spray <i>(appropriate wording to be specified by the manufacturer)</i> .
S24	Avoid contact with skin.
S25	Avoid contact with eyes.
S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S27	Take off immediately all contaminated clothing.
S28	After contact with skin, wash immediately with plenty of ... <i>(to be specified by the manufacturer)</i> .
S29	Do not empty into drains.
S30	Never add water to this product.
S31	<i>Deleted.</i>
S32	<i>Deleted.</i>
S33	Take precautionary measures against static discharges.
S34	Avoid shock and friction. <i>(No longer used)</i> .
S35	This material and its container must be disposed of in a safe way.
S36	Wear suitable protective clothing.

S37	Wear suitable gloves.
S38	In case of insufficient ventilation, wear suitable respiratory equipment.
S39	Wear eye/face protection.
S40	To clean the floor and all objects contaminated by this material, use ... <i>(to be specified by the manufacturer)</i> .
S41	In case of fire and/or explosion, do not breathe fumes.
S42	During fumigation/spraying, wear suitable respiratory equipment <i>(appropriate wording to be specified by the manufacturer)</i> .
S43	In case of fire, use ... <i>(Indicate in the space the precise type of fire-fighting equipment. If water increases the risk, add - Never use water)</i> .
S44	If you feel unwell, seek medical advice <i>(No longer used)</i> .
S45	In case of accident or if you feel unwell, seek medical advice immediately.
S46	If swallowed, seek medical advice immediately and show this container or label.
S47	Keep at temperature not exceeding ...°C <i>(to be specified by the manufacturer)</i> .
S48	Keep wetted with ... <i>(appropriate material to be specified by the manufacturer)</i> .
S49	Keep only in the original container.
S50	Do not mix with ... <i>(to be specified by the manufacturer)</i> .
S51	Use only in well-ventilated areas.
S52	Not recommended for interior use on large surface areas.
S53	Avoid exposure - obtain special instructions before use.
S54	Obtain the consent of pollution control authorities before discharging to wastewater treatment plants. <i>(No longer used)</i> .
S55	Treat using the best available techniques before discharge into drains or the aquatic environment. <i>(No longer used)</i> .
S56	Dispose of this material and its container at hazardous or special waste collection point.
S57	Use appropriate container to avoid environmental contamination.
S58	To be disposed of as hazardous waste. <i>(No longer used)</i> .
S59	Refer to manufacturer/supplier for information on recovery/recycling
S60	This material and its container must be disposed of as hazardous waste.
S61	Avoid release to the environment. Refer to special instructions/Safety data sheets
S62	If swallowed do not induce vomiting: seek medical advice immediately and show this container or label.

### Multiple Codes

S1/2	Keep locked up and out of the reach of children.
S3/7	Keep container tightly closed in a cool place.
S3/7/9	Keep container tightly closed in a cool, well-ventilated place.
S3/9/14	Keep in a cool, well-ventilated place away from ... <i>(Incompatible materials to be indicated by the manufacturer)</i> .
S3/9/14 /49	Keep only in the original container in a cool, well-ventilated place away from ... <i>(Incompatible materials to be indicated by the manufacturer)</i> .
S3/9/49	Keep only in the original container in a cool, well-ventilated place.
S3/14	Keep in a cool place away from ... <i>(Incompatible materials to be indicated by the manufacturer)</i> .
S7/8	Keep container tightly closed and dry.
S7/9	Keep container tightly closed and in a well-ventilated place.
S7/47	Keep container tightly closed and at temperature not exceeding ... °C <i>(to be specified by the manufacturer)</i> .

S20/21	When using do not eat, drink or smoke.
S24/25	Avoid contact with skin and eyes.
S27/28	After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of ... <i>(to be specified by the manufacturer)</i> .
S29/35	Do not empty into drains; dispose of this material and its container in a safe way.
S29/56	Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.
S36/37	Wear suitable protective clothing and gloves.
S36/37/ 39	Wear suitable protective clothing, gloves and eye/face protection.
S36/39	Wear suitable protective clothing and eye/face protection.
★ S37/39	Wear suitable gloves and eye/face protection.
S47/49	Keep only in the original container at temperature not exceeding ... °C <i>(to be specified by the manufacturer)</i> .



Annex I of Directive 67/548/EEC contains a list of harmonised classifications and labellings for substances or groups of substances, which are legally binding within the EU.

The list is regularly updated through Adaptations to Technical Progress (ATP). Revised and new classifications inserted to the list are proposed by DG ENV and agreed by a Member State vote.

The DG ENV proposal is based on advice from the Technical Committee for Classification and Labelling (TC C&L) with participation of experts from the Member States. Their meetings are prepared, chaired and followed-up by the ECB.

The following list is a compilation of those ATPs up to ATP 29 published in OJ L 152 of 30/04/2004.

Index No	Chemical name	Notes related to substances	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes related to preparations
001-001-00-9	hydrogen		215-605-7	1333-74-0	F+; R12	F+ R: 12 S: (2)-9-16-33		
001-002-00-4	aluminium lithium hydride		240-877-9	16853-45-3	F; R15	F R: 15 S: (2)-7/8-24/25-43		
001-003-00-X	sodium hydride		231-587-3	7646-69-7	F; R15	F R: 15 S: (2)-7/8-24/25-43		
001-004-00-5	calcium hydride		232-189-2	7789-78-8	F; R15	F R: 15 S: (2)-7/8-24/25-43		
003-001-00-4	lithium		231-102-5	7439-93-2	F; R14/15 C; R34	F; C R: 14/15-34 S: (1/2)-8-43-45		
003-002-00-X	n-hexyllithium		404-950-0	21369-64-2	F; R14/15-17 C; R35	F; C R: 14/15-17-35 S: (1/2)-6-16-26-30-36/37/39-43-45		
004-001-00-7	beryllium	E	231-150-7	7440-41-7	Carc. Cat. 2; R49 T+; R26 T; R25-48/23 Xi; R36/37/38 R43	T+ R: 49-25-26-36/37/38-43-48/23 S: 53-45		
004-002-00-2	beryllium compounds with the exception of aluminium beryllium silicates, and with those specified elsewhere in this Annex	AE	-	-	Carc. Cat. 2; R49 T+; R26 T; R25-48/23 Xi; R36/37/38 R43 N; R51-53	T+; N R: 49-25-26-36/37/38-43-48/23-51/53 S: 53-45-61		

Index No	Chemical name	Notes related to substances	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes related to preparations
613-079-00-7	4-(1(or 4 or 5 or 6)-methyl-8,9,10-trimethoxy-5-en-2-yl)pyridine, mixture of isomers		402-520-7	-	Xn; R21/22 Xi; R38 R43 N; R50-53	Xn; N R: 21/22-38-43-50/53 S: (2)-36/37-60-61		
613-080-00-2	3-bis(2-ethylthio)aminomethylbenzo thiazole-2(3H)-dione		402-540-6	105254-85-1	C; R34 R43 N; R50-53	C; N R: 34-43-50/53 S: (1/2)-26-28-36/37/39-45-60-61		
613-081-00-8	1-butyl-2-methylpyridinium bromide		402-680-8	26576-84-1	Xn; R22 R52-53	Xn R: 22-52/53 S: (2)-61		
613-082-00-3	2-methyl-1-methylpyridinium bromide		402-690-2	-	Xn; R21/22 R52-53	Xn R: 21/22-52/53 S: (2)-36/37-61		
613-083-00-9	2-(4-(3-(4-chlorophenyl)-2-pyrazolyl)-1-phenylsulfonyl)ethylidimethyl ammonium formate		402-120-2	-	C; R34 Xn; R48/22 R43 N; R50-53	C; N R: 34-43-48/22-50/53 S: (1/2)-24-26-28-37/39-45-60-61		
613-084-00-4	2-(4-(3-(4-chlorophenyl)-4,5-dihydro-1H-pyrazol-1-yl)ethylidimethylammonium hydrogen phosphate		402-490-5	106359-93-7	Xi; R36 N; R50-53	Xi; N R: 36-50/53 S: (2)-26-60-61		
613-085-00-X	Mixture of 1,1'-(methylenedioxy)-4,1-phenylenebis(4,1-phenylene)dipyrrole-2,5-dione and N-(4-(4-(2,5-dioxypyrrol-1-yl)benzyl)phenyl)acetamide and 1-(4-(4-(5-oxo-2H-pyrrolo[2,5-dione]pyrrole-2,5-dione)pyrrole-2,5-dione)pyrrole-2,5-dione)pyrrole-2,5-dione		401-970-1	-	R43 N; R50-53	Xi; N R: 43-50/53 S: (2)-24-37-60-61		
613-086-00-5	caffeine		200-362-1	58-08-2	Xn; R22	Xn R: 22 S: (2)-		
613-087-00-0	tetrahydrothiophene		203-728-9	110-01-0	F; R11 Xn; R20/21/22 Xi; R36/38 R52-53	F; Xn R: 11-20/21/22-36/38-52/53 S: (2)-16-23-36/37-61		
613-088-00-6	1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one		220-120-9	2634-33-5	Xn; R22 Xi; R38-41 R43 N; R50	Xn; N R: 22-38-41-43-50 S: (2)-24-26-37/39-61	C ≥ 25 %: Xn; N; R22-38-41-43-50 20 % ≤ C < 25 %: Xi; R38-41-43 10 % ≤ C < 20 %: Xi; R41-43 5 % ≤ C < 10 %: Xi; R36-43 0,05 % ≤ C < 5 %: Xi; R43	
613-089-00-1	diquat dibromide; [1] diquat dichloride; [2]		201-579-4 [1]	85-00-7 [1] 4032-26-2 [2]	T+; R26 T; R48/25	T+; N R: 22-26-36/37/38-43-48/25-		

Avis juridique important

**31967L0548**

**Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances**

*Official Journal 196, 16/08/1967 P. 0001 - 0098*

*Finnish special edition: Chapter 15 Volume 1 P. 0019*

*Danish special edition: Series I Chapter 1967 P. 0211*

*Swedish special edition: Chapter 15 Volume 1 P. 0019*

*English special edition: Series I Chapter 1967 P. 0234*

*Greek special edition: Chapter 13 Volume 1 P. 0034*

*Spanish special edition: Chapter 13 Volume 1 P. 0050*

*Portuguese special edition Chapter 13 Volume 1 P. 0050*

COUNCIL DIRECTIVE of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (67/548/EEC)

THE COUNCIL OF THE EUROPEAN ECONOMIC COMMUNITY,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof;

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament (1);

Having regard to the Opinion of the Economic and Social Committee (2);

Whereas any rules concerning the placing on the market of dangerous substances and preparations must aim at protecting the public, and in particular workers using such substances and preparations;

Whereas the differences between the national provisions of the six Member States on the classification, packaging and labelling of dangerous substances and preparations hinder trade in these substances and preparations within the Community and hence directly affect the establishment and functioning of the common market;

Whereas it is therefore necessary to remove such hindrances ; whereas this entails approximating the laws, regulations and administrative provisions on classification, packaging and labelling;

Whereas, in view of the preparatory work still to be carried out, the approximation of provisions relating to dangerous preparations will have to be dealt with in later directives ; whereas therefore the present Directive must be restricted to the approximation of provisions relating to dangerous substances;

Whereas in view of the extent of this field and the many detailed measures which will be required for the approximation of all the provisions relating to dangerous substances, it would appear advisable to deal first with the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances and to deal in later directives with the approximation of the provisions relating to the use of those dangerous substances and preparations if it is established that the differences between such provisions directly affect the establishment or functioning of the common market;

Whereas the approximation of national provisions which is laid down by this Directive does not prejudice application of the provisions of Articles 31 and 32 of the Treaty;

HAS ADOPTED THIS DIRECTIVE:



## Article 1

1. The purpose of this Directive is to approximate the laws, regulations and administrative provisions of the Member States on: - classification,

- packaging, and
- labelling

of dangerous substances which are placed on the market in the Member States of the Community.

2. This Directive does not affect the provisions relating to: (a) medicinal products, narcotics and radioactive substances ; (1) OJ No 209,11.12.1965, p. 3133/65. (2) OJ No 11,20.1.1966, p. 143/66.

(b) the carriage of dangerous substances by rail, road, inland waterway, sea or air;

(c) munitions and objects containing explosive matter in the form of igniters or motor fuels.

3. This Directive does not apply to dangerous substances exported to third countries.

4. Articles 5 to 7 of this Directive do not apply to containers for gases which are compressed, liquefied or dissolved under pressure.

## Article 2

1. For the purposes of this Directive: (a) "substances" means chemical elements and their compounds as they occur in the natural state or as produced by industry;

(b) "preparations" means

mixtures or solutions composed of two or more substances.

2. The following substances and preparations are "dangerous" within the meaning of this Directive: (a) explosive:

substances and preparations which may explode under the effect of flame or which are more sensitive to shocks or friction than dinitrobenzene;

(b) oxidising:

substances and preparations which give rise to highly exothermic reaction when in contact with other substances, particularly flammable substances;

(c) easily flammable: - substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or

- solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or

- liquid substances and preparations having a flash point below 21° C, or

- gaseous substances and preparations which are flammable in air at normal pressure, or

- substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities;

(d) flammable:

liquid substances and preparations having a flash point between 21° C and 55° C;

(e) toxic:

substances and preparations which, if they are inhaled or taken internally or if they penetrate the skin, may involve serious, acute or chronic health risks and even death;

(f) harmful:

substances and preparations which, if they are inhaled or taken internally or if they penetrate the skin, may involve limited health risks;

(g) corrosive:

substances and preparations which may, on contact with living tissues, destroy them;

(h) irritant:

non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, can cause inflammation.

#### Article 3

The classification of dangerous substances according to the greatest degree of hazard and specific nature of the risks shall be based on the categories laid down in Article 2.

#### Article 4

Annex I to this Directive gives the list of dangerous substances classified in accordance with the provisions of Article 3.

#### Article 5

Member States shall take all necessary measures to ensure that dangerous substances cannot be placed on the market unless the strength and impermeability of their packaging satisfies the following requirements, any packaging meeting these requirements being regarded as adequate:

1. The packagings must be so arranged and fastened as to preclude any loss of the contents ; this requirement does not apply where special safety devices are prescribed;
2. The materials constituting the packaging and fastenings must not be liable to attack by the contents, or liable to form harmful or dangerous compounds with the contents ;
3. The packagings and fastenings must be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling.

#### Article 6

1. Member States shall take all necessary measures to ensure that dangerous substances cannot be placed on the market unless the labelling on their packaging satisfies the following requirements.

2. All packagings must be labelled with: - the name of the substance,
  - the origin of the substance,
  - the danger symbol and indication of danger involved in the use of the substance,
  - a reference to the special risks arising from such dangers;

(a) the name of the substance must be one of the terms listed in Annex I to this Directive;

(b) the indication of origin must include the name and address of the manufacturer, the distributor or the importer;

(c) the following symbols and indications of danger are to be used:

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The symbols must conform to those in Annex II to this Directive ; they shall be printed in black on an orange-yellow background.

(d) The nature of the special risks involved in using the substances must be indicated by one or more of the standard phrases which, in conformity with the references contained in the list in Annex I, are set out in Annex III to this Directive.

3. If the packaging is accompanied by advice on safety precautions relating to the use of the substances, the wording of this shall, in conformity with the references contained in the list in Annex I, be taken from Annex IV to this Directive.

#### Article 7

1. Where the particulars required by Article 6 appear on a label, that label must be placed on one or more surfaces of the packaging so that it can be read horizontally when the package is set down normally. The dimensions of the label must not be less than those of a standard A 8 sheet (52 X 74 mm), but there is no obligation that it exceed those of a standard A 5 sheet (148 x 210 mm). Each symbol must cover at least one-tenth of the surface area of the label. The entire surface of the label must stick to the immediate packaging of the substance.

2. A label shall not be required where the particulars are clearly printed on the normal packaging as specified in paragraph 1.

3. The particulars on the packaging or on the label must be printed in clearly legible and indelible characters so as to ensure that the symbols and indications of danger and the reference to special risks are sufficiently prominent.

4. Member States may make the placing on the market of dangerous substances in their territories subject to the use of the national language or languages in the labelling of these substances.

5. The obligations of paragraphs 1 to 4 concerning labelling shall be regarded as being satisfied where a container is dispatched bearing a label complying with the dispatch requirements and where this label displays the appropriate symbol laid down in Article 6 (2) (c). This derogation shall not apply to containers which are inside other containers.

#### Article 8

Member States may (a) permit the labelling required by Article 6 to be affixed in some other appropriate manner on packaging too small to allow labelling in accordance with Article 7 (1) or (2);

(b) by way of derogation from Articles 6 and 7, permit the packaging of dangerous substances which are neither explosive nor toxic to be unlabelled, or to be labelled in some other way if they contain such small quantities that there is no danger to workers or others.

#### Article 9

Member States shall inform the Commission of all laws, regulations and administrative provisions which they adopt in the field covered by this Directive.

#### Article 10

Member States shall adopt the measures needed in order to comply with this Directive and shall apply them by 1 January 1970 at the latest.

They shall forthwith inform the Commission thereof.

#### Article 11

This Directive is addressed to the Member States.

Done at Brussels, 27 June 1967.

For the Council

The President

R. VAN ELSLANDE

Annex I to this Directive is not reproduced in this edition as its repeal and replacement are provided for in the Proposal for a Directive submitted by the Commission to the Council on 30 December 1971 and published in the Official Journal of the European Communities, No C 34 of 7 April 1972, page 11.

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